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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,112	11/20/2000	Britton Chance	08326-046002	9950
26161	7590	10/09/2003	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			SMITH, RUTH S	
			ART UNIT	PAPER NUMBER
			3737	
DATE MAILED: 10/09/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,112

Applicant(s)

CHANCE, BRITTON

Examiner

Ruth S Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Objections

Claims 10,16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependant claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims 1-9,11-15,17-35 are objected to because of the following informalities: In claims 1,4,5, line 5, "the biological tissue" lacks antecedent basis. In claims 1,4,5,17,19,25 "said light source" and "said light detector" lack antecedent basis in that they have not been positively set forth as part of the claimed invention. In claims 1,4,5 lines 12/13, "said detector" lacks antecedent basis. It is unclear as to how claim 2 sets forth a further structural limitation in the system. In claim 13 "said source" and "said detector" lack antecedent basis. In claim 18, it is unclear as to which detector is being referred to on line 3. In claim 35, line 11, "at" should be inserted before "least". Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-9,11-15,17-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a light source and a light detector.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,6-9,11-15,17,18,29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance et al (5,853,370). Chance et al disclose a method and apparatus for examining tissue optically using an optical module having input and output ports, a controller and a processor. A plurality of data sets are provided that include data representing both blood volume and blood oxygenation (column 8, lines 23-48). The data sets are subtracted to obtain a difference data set. It would have been obvious to one skilled in the art to have used the images to determine an abnormality present in the patient in that the use of such information for this purpose is a well known expedient in the art. With respect to claim 6, it can be seen from figures 7-7A that a plurality of optical modules can be used to acquire data from a plurality of locations on the patient. With respect to claims 7-9, the manner in which the data from the two data sets are compared would have been an obvious design choice of known functional equivalents in the art.

Claims 3-9, 11-15,17,18,29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance et al (5,853,370) in view of Hochman et al (5,845,639). Chance et al disclose a method and apparatus for examining tissue optically using an optical module having input and output ports, a controller and a processor. A plurality of data sets are provided that include data representing both blood volume and blood oxygenation (column 8, lines 23-48). The data sets are subtracted to obtain a difference data set. It would have been obvious to one skilled in the art to have used the images to determine an abnormality present in the patient. With respect to claim 6, it can be seen from figures 7-7A that a plurality of optical modules can be used to acquire data from a plurality of locations on the patient. With respect to claims 7-9, the manner in which the data from the two data sets are compared would have been an obvious design choice of known functional equivalents in the art. Chance et al fail to disclose the use of a reference to compared the data against to aid in making a diagnosis. Hochman et al is just one example of many which disclose an optical system for analyzing tissue by comparing data obtained from the examine tissue with data obtained from a reference sample having a known condition. It would have been

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obvious to one skilled in the art to have modified Chance et al such that the data is compared to a reference sample in that is such a well known expedient in the art to ensure an accurate diagnosis.

Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance et al (5,853,370) in view of Chance (5,564,417)). Chance et al ('370) disclose a method and apparatus for examining tissue optically using an optical module having input and output ports, a controller and a processor. A plurality of data sets are provided that include data representing both blood volume and blood oxygenation (column 8, lines 23-48). The data sets are subtracted to obtain a difference data set. It would have been obvious to one skilled in the art to have used the images to determine an abnormality present in the patient. Chance et al fail to disclose the specific structure of the spectrophotometer to process the emitted and detected light. Chance ('417) discloses a system for imaging tissue optically using the specific optical structure as set forth in claims 19-24. It would have been obvious to one skilled in the art to have further modified Chance et al such that it includes the optical system structure as set forth in Chance. Such a modification merely involves the substitution of one well known spectrophotometer arrangement for another.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance et al (5,853,370) in view of Chance (5,807,263)). Chance et al ('370) disclose a method and apparatus for examining tissue optically using an optical module having input and output ports, a controller and a processor. A plurality of data sets are provided that include data representing both blood volume and blood oxygenation (column 8, lines 23-48). The data sets are subtracted to obtain a difference data set. It would have been obvious to one skilled in the art to have used the images to determine an abnormality present in the patient. Chance et al fail to disclose the specific structure to process the emitted and detected light. Chance ('263) discloses a system for imaging tissue optically using the specific optical structure as set forth in claims 25-28. It would have been obvious to one skilled in the art to have further modified Chance et

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al such that it includes the optical system structure as set forth in Chance. Such a modification merely involves the substitution of one well known spectrophotometer arrangement for another.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-34 of copending Application No. 09/622,184. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. It should be noted that the intended use of the apparatus does not impose further limitations on the claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claim 35 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 35 of copending Application No. 09/622,184. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one skilled in the art to have used the optical system on any part of the patient's body.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Ruth S Smith
Primary Examiner
Art Unit 3737

RSS